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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,966	12/03/2003	Catherine A. Pipenhagen	47563.0012	4374
57600 7590 03/20/2008 HOLLAND & HART LLP P.O. Box 11583 60 E. South Temple, Suite 2000 Salt Lake City, UT 84110				
EXAMINER				
WOO, JULLAN W				
ART UNIT		PAPER NUMBER		
3773				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/726,966

Applicant(s)

PIPNHAGEN ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-33, 37-40 and 42-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 7-9, 14, 15, 19, 20, 22, 23, 25, 28-31, 33, 37-40, 42, 43, and 45-54 is/are rejected.
- 7) ☒ Claim(s) 3, 10-13, 16-18, 21, 24, 26, 27, 32, 44 and 55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 4, 2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 15, 19, 20, 22, 23, and 47-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Rousseau (6,425,924). Rousseau discloses, in figures 1-4 and col. 4, line 61 to col. 5, line 1; a tissue puncture closure device in an undeployed configuration having a filament (22), an internal component (distal element 14), an external component including another, proximal element 14 as a first external

component and element 26 as a second external component; where the internal component is configured to be positioned against an internal wall of a bodily lumen and comprises a stiff member (pleated mesh), where the external component is configured to be positioned external to the lumen, the external component being folded so one portion of the external component is in contact with another portion of the external component (at the folds), where the external component is operatively connected to the internal component by the filament, where the sealing plug comprises first (at 26) and second (at 14) pluralities of openings (the cells of the meshes), where the filament passes through one hole or first portion of a weave pattern in the external component to a hole in the internal component and back through another hole or a second portion of the weave pattern in the external component, the external component being folded between the one hole and the another hole in the external component, where the where the filament only passes once through each one of the hole and the another hole, and where a tension force applied to the filament compresses the sealing plug and the moves the sealing plug toward the anchor (See fig. 4).

4. Claims 28-31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (5,531,759). Kensey et al. disclose, at least in figures 1-6 , 9, and 13; a tissue puncture sealing device including a filament (42), an anchor (38) attached to the filament, a sealing plug (36) disposed proximal of the anchor, the sealing plug including a plurality of openings (48 and 50 on one leg of 36) and a second plurality of openings (48 and 50 on the other leg of 36), where the filament passes through at least two openings from the first plurality of openings, through the anchor, and back through at

least two openings from the second plurality of openings, where the filament weaves between the anchor and the first plurality of openings in a nonlinear pattern, where the sealing plug is folded and the tissue puncture sealing device is in an undeployed configuration (e.g., see fig. 1), and where the sealing plug has two legs (two sides of 36 when folded) that form an at least approximately symmetrical shape, and where the plurality of openings are in one leg and the second plurality of openings are in another leg. Kenney et al. also disclose a tissue puncture sealing device including an insertion sheath (34) having first and second ends, a carrier tube (32), an anchor (38) disposed inside the insertion sheath at the first end thereof and outside of the carrier tube at the first end thereof (at a stage of deployment of the anchor between figures 1 and 2), a sealing plug (36) disposed inside the carrier tube at the first end thereof, where the sealing plug is folded at least once (See fig. 6), where the tissue puncture device is in an undeployed configuration where the tissue puncture device is not inserted into a patient (e.g., at assembly of the device or at demonstration of the device outside of a patient); and where the sealing plug is folded from an original V-shape (see fig. 6) to a rectangular shape (see fig. 1).

5. Claims 53 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Doan et al. (5,792,154). Doan et al. disclose, at least in figure 6 and in col. 4, line 56 to col. 5, line 4; a tissue puncture closure device including an anchor (137) configured to be inserted through a tissue puncture, a sealing plug (143) including separate first and second components (separate fibers 143), a filament (139 or 141) configured to couple the anchor and the sealing plug together when the anchor and the sealing plug are

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deployed, where the first and second components each have a U-shape and are in an interconnected relationship to each other.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 1, 2, 4, 5, 8, 9, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rousseau (6,425,924) in view of Eberbach (5,116,957). Rousseau discloses the invention substantially as claimed. Rousseau discloses a tissue puncture closure device including a filament passes through one hole in a sealing plug to a hole in an anchor and back through another hole in the sealing plug, where the sealing plug (at 14) is folded at least twice or between the first and second weave patterns, where the sealing plug is folded between the one hole in the sealing plug and the another hole in the sealing plug, where the first and second weave patterns each include a five-hole

zigzag arrangement (i.e., each weave pattern includes cells on alternating on both sides of a pleat), where the sealing plug and filament each comprise biologically resorbable materials (See col. 4, lines 41-56), and the sealing plug shape comprises two components (14 and 26). However, Rousseau does not disclose a carrier tube. Eberbach teaches, at least in figure 7 and in col. 3, lines 29-37; a carrier tube (10) for a tissue puncture closure device. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Eberbach, to include a carrier tube with the device of Rousseau. Such a tube would allow the precise delivery of Rousseau's device through a laparoscopic opening and into a surgical cavity without substantial interference from surrounding tissues.

8. Claims 25 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmieding (6,027,523) in view of Walter et al. (5,716,413). Schmieding discloses the invention substantially as claimed. Schmieding discloses, in figure 11, an internal tissue puncture closure device including an anchor (50, 52, 54, or 56), a filament, and a sealing plug (42), where the sealing plug includes two cross members, where the sealing plug is formed of PLLA, where applying a tension force to the filament moves the anchor and sealing plug together, and where the sealing plug is generally X-shaped in cross-section. However, Schmieding does not disclose that the filament extends through a plurality of holes in each of the two cross members, where the sealing plug is configured to compress when a tension force is applied to the filament. Nevertheless, Schmieding discloses a sealing plug (4) with a plurality of holes for receiving filaments (6, 36), where filaments 6 include knots configured to press upon the sealing plug when

a tension force is applied to the filament. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to include a plurality of holes in each of the two cross members. Such holes would allow convenient attachment of filaments to the sealing plug, while allowing at least two portions of a filament or two filaments to securely connect the sealing plug (and tissue) to the anchor. Moreover, filaments with knots applied with the sealing plug would allow compression of the sealing plug when tension is applied to the filament and allow a better securement of tissue to the anchor. Schmieding also does not disclose that the sealing plug is flexible or compressible. Walter et al. teach, at least in col. 4, line 49 to col. 5, line 13 and col. 7, lines 30-57, that PLLA may be flexible at room temperature or at body temperature, yet retain structural integrity. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply flexible PLLA in the sealing plug of Schmieding. Such a modification would allow the sealing plug to conform to the contours of soft tissue and allow improved bonding between the plug and tissue and reduce the possibility of chafing between the plug and other tissues surrounding the plug.

9. Claims 31, 37-40, 42, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt et al. (6,508,828). Akerfeldt et al. disclose the invention substantially as claimed. Akerfeldt et al. disclose, in figures 1, 4, and 6-18, a tissue puncture closure device and a method of sealing an internal tissue puncture having a carrier tube (24) or insertion sheath, and a closure device including an anchor (2) and a sealing plug (18) that is folded at least once or from a V-shape (fig. 18) into a

substantially straight shape, and a filament (12), where applying a tension force to the filament compresses and holds the sealing plug and the anchor together (e.g., See figures 1 and 4). However, Adkerfeldt et al. do not disclose that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug, when the closure device is in an undeployed configuration before insertion into the internal tissue puncture (see fig. 8). Akerfeldt et al. also do not disclose that the sealing plug is in a V-shape when open and laid out flat. Nevertheless, Akerfeldt et al. disclose, in figures 15 and 17, that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug when parts 41 and 42 are moved along filament (12). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to move parts 41 and 42 within the carrier tube (as shown in figures 8, 10, and 11), so that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug (while the closure device is in an undeployed configuration within the carrier tube). Such a narrowed configuration of the sealing plug would ease its deployment through a puncture in a vessel. Akerfeldt et al. also disclose, in col. 5, lines 4-7; that the sealing plug (18) comprises a polymeric material conforming to a suture (12) and is a thickened portion of a suture formed into a V-shape. Thus, it would have been obvious to one having ordinary skill in the art to form the sealing plug into a V-shape while the suture is open and laid out flat in a V-shape. Such a pre-formed shape for the sealing plug and suture would ease the assembly of the components of the device before its insertion into a tissue wall puncture.

Akerfeldt et al. also do not disclose that the anchor is positioned outside of the carrier tube. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to position the anchor outside of the carrier tube before its insertion within the carrier tube in a known technique of assembling the device prior to its deployment.

Allowable Subject Matter

10. Claims 3, 10-13, 16-18, 21, 24, 26, 27, 32, 44, and 55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination discloses a tissue puncture closure device having, inter alia, a carrier tube, a filament, an anchor, and a sealing plug or first external component, and a second external component folded and engaged with the first external component, where the sealing plug is shaped approximately like an S, where the external component is collagen sponge where the sealing plug comprises an X-shape in cross-section and the filament alternately extends through holes in two cross members of the sealing plug in a spiral pattern, where the external component comprises two legs folded along a centerline, where the sealing plug is tri-folded into an S-shape as seen from an end, and where first and second external components are each folded into generally U-shapes and the filament passes through one hole in the first component and one hole in the second component before

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passing through a hole in the anchor, and where the filament passes through another hole in the first component and another hole in the second component after passing through the hole in the anchor.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

12. Applicant's arguments filed on August 10, 2007 have been fully considered but they are not fully persuasive: See the restated and new grounds of rejection above.

With respect to arguments regarding the rejection of claims 15 and 47-52: Rousseau indeed discloses an internal component or an anchor comprising a "stiff member." Cones 14, if stood up on their bases, would not collapse, because the pleats, according to Rousseau, "enhance the axial rigidity" of the cones. In other words, the cones are stiffened by the pleats.

With respect to claims 25, 28-30, and 43, new grounds of rejection are presented.

With respect to claims 31 and 33, Kensey indeed discloses an insertion sheath as claimed.

With respect claims 53 and 54, the arguments regarding the application of the Doan reference are directed to the intended use of Doan's device. Applicant is reminded that it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed

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apparatus from a prior art apparatus satisfying the claimed structural limitations. Moreover, element 137 of Doan's device may be considered an "anchor," in that it may engage a vessel wall and/or embolic material. may be attached to or anchored to the element.

With respect to claims 1, 2, 4, 5, 8, and 14, the rejection is maintained, since independent claim 1 was not rewritten in independent form to include all of the limitations of the base claim 6 and the intervening claims.

With respect to claims 31, 37-40, 42, 45, and 46 and the rejections based on Akerfeldt: Element 18 indeed is a sealing plug in that it does provide at least partial filling of a tissue puncture. It is not only used to thicken a suture wire; it is also a foldable "component" (Applicant's term for the distinct element) as claimed.

The rejection under 35 U.S.C. 112, 2nd paragraph, is hereby withdrawn.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

March 27, 2008